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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,731	02/19/2008	Bakulesh Mafatal Khamar	21059/0206949-us0	8375
7278	7590	12/23/2008		
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER SWARTZ, RODNEY P	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 12/23/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/583,731

**Applicant(s)**

KHAMAR ET AL.

**Examiner**

Rodney P. Swartz, Ph.D.

**Art Unit**

1645

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 and 29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26, 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/5508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

#### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 25 September 2008, is acknowledged. Claims 1, 3-18, 22-26 and 29 have been amended.
2. Claims 1-26 and 29 are pending and under consideration.

#### **Rejections/Objections Withdrawn**

3. The objection to claims 1, 2, 4-7, 10-16, and 29 because occurrences of "Mycobacterium w" should be in italics, is withdrawn in light of the amendment of the claims.
4. The objection to claim 7 because "ingredient" should be "gradient" is withdrawn in light of the amendment of the claim.
5. The objection to claim 17 because in line 5, "antigen" should be "antigens" is withdrawn in light of the amendment of the claim.
6. The objection to claim 25 because in line 3, "morlatity" should be "mortality" is withdrawn in light of the amendment of the claim.
7. The rejection of claim 12 under 35 U.S.C. 112, second paragraph, as being indefinite for not ending with a period, is withdrawn in light of the amendment of the claim.

The rejection of claim 13 under 35 U.S.C. 112, second paragraph, as being indefinite for the modifier "preferably" is withdrawn in light of the amendment of the claim.

8. The rejection of claim 14 under 35 U.S.C. 112, second paragraph, as being indefinite for the term "resembling", is withdrawn in light of the amendment of the claim.
9. The rejection of claim 15 under 35 U.S.C. 112, second paragraph, as being indefinite for the trademark/trade name TWEEN 80, is withdrawn in light of the amendment of the claim.

The rejection of claim 17 under 35 U.S.C. 112, second paragraph, as being indefinite for an antigen encoded "in" nucleic acids, is withdrawn in light of the amendment of the claim.

### **Rejections/Objections Maintained**

10. The objection to claims 3, 8 and 9 because occurrences of "Mycobacterium w" should be in italics, is maintained because not all occurrences have been corrected.

11. The rejection of claims 1-17, 22-26 and 29 under 35 U.S.C. 102(b) as being anticipated by Khamar et al (WO 03/049667) is maintained.

Applicants argue that Khamar et al do not teach a composition with an antigen therein. Applicants argue that the examiner has inadvertently rejected claim 16 and 17 even the claims specifically recite an antigen.

The examiner has considered applicants arguments, but does not find them persuasive. Firstly, claim 16 does not designate any particular antigen and claim 17 recites that the antigen may be one or more peptides without restricted the source of the peptides. Claim 1 is a composition comprising *Mycobacterium w* or constituents thereof, an antigen, and a carrier. Since *Mycobacterium w* comprises peptides, the *Mycobacterium w* may serve both as the antigen and the adjuvant. The claims do not restrict the source of the antigen.

12. The rejection of claims 1-17, 22-26 and 29 under 35 U.S.C. 102(b) as being anticipated by Khamar et al (WO 03/075825) is maintained.

Applicants argue that Khamar et al do not teach a composition with an antigen therein. Applicants argue that the examiner has inadvertently rejected claim 16 and 17 even the claims specifically recite an antigen.

The examiner has considered applicants arguments, but does not find them persuasive. Firstly, claim 16 does not designate any particular antigen and claim 17 recites that the antigen may be one or more peptides without restricted the source of the peptides. Claim 1 is a composition comprising *Mycobacterium w* or constituents thereof, an antigen, and a carrier.

Since *Mycobacterium w* comprises peptides, the *Mycobacterium w* may serve both as the antigen and the adjuvant. The claims do not restrict the source of the antigen.

13. The rejection of claims 19-21 under 35 U.S.C. 112, second paragraph, as being indefinite for dependence from rejected claims, is maintained.

#### **New Rejection Necessitated by Amendment**

##### **Claim Rejections - 35 USC § 112**

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is now dependent from a rejected claim.

#### **Conclusion**

16. No claims are allowed.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a)

will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

December 18, 2008